IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Attorney Docket No. 011738.00133

In re the Application of:		Atty. Docket No.:	011738.00133
Osorio, *et al.*			
Serial No.:	10/687,135	Group Art Unit:	3762
Filed:	October 15, 2003	Examiner:	Alyssa M. Alter
For:	CONFIGURING AND TESTING TREATMENT THERAPY PARAMETERS FOR A MEDICAL DEVICE SYSTEM	Confirmation No.:	8261

BRIEF ON APPEAL

MS: Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §41.37, Appellant submits this Appeal Brief to the Board of Patent Appeals and Interferences in response to the Final Rejection mailed on July 21, 2009. The Commissioner is authorized to charge any fees owed or credit any overpayment of fees to Deposit Account No. 19-0733.

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I. Real Party in Interest

The real party in interest is Medtronic, Inc., the owner of the entire right, title and interest in and to the subject application.

II. Related Appeals and Interferences

There are no appeals or interferences related to the subject appeal.

III. Status of the Claims

Claims 1-37, which are involved in the appeal, stand finally rejected by an Office Action mailed July 21, 2009 and are found in the Appendix. No claim is allowed.

IV. Status of Amendments

No after final amendments were requested or are pending.

V. Summary of Claimed Subject Matter

The pending claims 1-37 are directed toward an apparatus and method that configures and tests treatment therapy parameters. (Specification, pg. 1, ¶ 2, ln. 2-3). Claims 1 and 25 are independent.

Turning to independent claim 1, the step of "receiving a first set of information from a user, the first set of information being associated with a first treatment therapy configuration" is recited and an embodiment of this is described in the specification on pg. 35-36, ¶ 116, ln. 20-22. Next the step of "assessing whether the first set of information is within a range of safety" is recited and an embodiment of this is described in the specification on pg. 36-37, ¶ 117, ln. 1 – ¶ 118, ln. 6. Then the step of "applying a first treatment therapy to a patient in accordance with the first set of information" is recited and an embodiment of this is described in the specification on pg. 37, ¶ 119, ln. 1-13. Next the step of "if the first treatment therapy is not safe, executing a corrective action" is recited and an embodiment of this is described in the specification on pg. 37, ¶ 119, ln. 9-12. Then the step of "if the first treatment therapy is safe, storing the first set of information for subsequent use" is recited and an embodiment of this is described in the specification on pg. 35-36, ¶ 116, ln. 20-22.

Turning to independent claim 25, which is directed toward an apparatus, the feature "a user interface" is recited and an embodiment of this is described in the specification on pg. 3, ¶ 7, ln. 8-9. Next, the feature "a treatment therapy module" is recited and an embodiment of this is described in the specification on pg. 3, ¶ 7, ln. 1-13 and pg. 8-9, ¶ 48, ln. 1-12. Then, the feature "a memory" is recited and an embodiment of this is described in the specification on pg. 8-9, ¶ 48, ln. 1-12. Next, the feature "a processor that is connected to the user interface in order to receive a command from a user and to send a response to the user and that instructs the treatment

therapy module" is recited and an embodiment of this is described in the specification on pg. 8-9, ¶ 48, ln. 1-12. Claim 25 then recites that the processor is configured to perform "receiving a first set of information from the user through the user interface, the first set of information being associated with a first treatment therapy configuration" and an embodiment of this is described in the specification on pg. 35-36, ¶ 116, ln. 20-22. Claim 25 next recites that the processor is configured to perform "assessing whether the first set of information is within a range of safety" and an embodiment of this is described in the specification on pg. 36-37, ¶ 117, ln. 1 – ¶ 118, ln. 6. Claim 25 then recites that the processor is configured to perform "applying a first treatment therapy to a patient through the treatment therapy module in accordance with the first set of information" and an embodiment of this is described in the specification on pg. 37, ¶ 119, ln. 1-13. Claim 25 next recites that the processor is configured to perform "if the first treatment therapy is not safe, executing a corrective action" and an embodiment of this is described in the specification on pg. 37, ¶ 119, ln. 9-12. Claim 25 then recites that the processor is configured to perform "if the first treatment therapy is safe, storing the first set of information in the memory, wherein the first set of information is accessible for a subsequent treatment therapy" and an embodiment of this is described in the specification on pg. 36, ¶ 117, ln. 1 – pg. 37, ¶ 120, ln. 7.

Regarding the dependent claims, claim 7 depends from claim 6, which recites the feature "associating a first label with the first set of information" and claim 7 recites the feature "receiving the first label from the user" and further recites the feature "applying a subsequent treatment therapy in accordance with the first label" an embodiment of this is at least found in the specification as filed, pg 3, ¶ 8, ln. 1-3 and pg. 35-36, ¶ 116, ln. 20-22. Claim 8 recites the feature "receiving another set of information from the user, the other set of information being associated with another treatment therapy configuration" and the feature of "associating another

label with the other set of information" and the feature of "comparing the first set of information and the other set of information" and an embodiment of this is at least found in the specification as filed, pg. 35, ¶ 116, ln. 22-24. Claim 9 recites the feature of "if the other treatment therapy configuration is essentially unique, storing the other set of information and the other label" and an embodiment of this is disclosed in the specification as filed, pg. 35, ¶ 116, ln. 22-24. Claim 10 recites the feature of "if the other treatment therapy configuration is not essentially unique, outputting a notification to the user" and an embodiment of this is disclosed in the specification as filed, pg. 35, ¶ 116, ln. 22-24. Claim 14 recites the feature "determining a surface area of the electrode" and the feature of "determining a charge density that is associated with the electrode" and the feature of "if the charge density is greater than a predetermined threshold, rejecting the first set of information in order that the first treatment therapy corresponding to the first set of information is not delivered to the patient" and an embodiment of this is disclosed in the specification as filed, pg. 36, ¶ 117, ln. 1-12. Claim 28 depends from claim 27, which recites the feature "associating a first label with the first set of information" and claim 28 recites the features of "receiving another set of information from the user, the other set of information being associated with another treatment therapy configuration" and the feature of "associating another label with the other set of information" and the feature of "comparing the first set of information with the other set of information" and an embodiment of this is at least found in the specification as filed, pg. 35, ¶ 116, ln. 20-24. Claim 32 recites the features of "determining a surface area of the electrode" and "determining a charge density that is associated with the electrode" and "if the charge density is greater than a predetermined threshold, rejecting the first set of information in order that the first treatment therapy corresponding to the first set of information is not delivered

to the patient" and an embodiment of this is disclosed in the specification as filed, pg. 36, ¶ 117, ln. 1-12.

VI. Grounds of Rejection to be Reviewed on Appeal

Claims 1-6, 12-13, 17, 20, 22-31 and 33-36 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Pub. No. 2001/0034542 to Mann (Mann). Claims 7-11 and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mann or the modified Mann as applied to claims 1-6, 12-13, 17, 20, 22-31, and 33-36 above. Claims 14-16 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mann, or the modified Mann as applied to claims 1-6, 12-13, 17, 20, 22-31, and 33-36 above, in view of U.S. Patent Pub. No. 2004/0015205 to Whitehurst *et al.* (Whitehurst). Claims 18-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mann or the modified Mann as applied to claims 1-6, 12-13, 17, 20, 22-31, and 33-36 above, in view U.S. Patent No. 6,594,524 to Esteller *et al.* (Esteller). The rejection for claims 1-37 is being appealed.

VII. Argument

The discussion below, unless otherwise noted, addresses the rejected independent claims 1, 25 and dependent claims 7-11, 14-16 and 28-32. As will be discussed below, the rejection of independent claims 1 and 25, as well as the rejection of dependent claims 7-11, 14-16 and 28-32 should be reversed. Appellants respectfully request that the rejection of the remaining dependent claims 2-6, 12-13, 17-27 and 33-37 be reversed for at least the reasons supporting reversal of the rejection of the independent claims from which they depend and for the additional limitations recited therein.

A. Contrary to the Examiner's Suggestion, Mann Does Not Expressly or Inherently Disclose the Feature "assessing whether the first set of information is within a range of safety," and the Rejection of Claim 1 is Not Supported By Mann.

Claim 1 is directed toward a method that includes the step of "assessing whether the first set of information is within a range of safety." In the Final Office Action, the Examiner suggested that Mann disclosed this, pointing to pg. 2, paragraphs 11-12 of Mann. In particular, the Examiner stated:

Applicant's arguments filed April 14, 2009 have been fully considered but they are not persuasive.

The Applicant argues that Mann (US Patent Publication 20010034542 A1) does not discloses a "range of safety". Furthermore, the Applicant states that "they are unaware of any support for the Examiner's proposition that the range between a minimum perception level and a maximum tolerable level is the same as a range of safety". However, the examiner stated in the Office Action on page 10, "the Applicant describes on page 14, paragraph 125, "the treatment therapy configuration is within a configuration range of safety. Safety to the patient is gauged by an expectation that the treatment does not diminish the health of the patient". Therefore, since the stimulation is in a range of a minimum perception threshold level, a maximum tolerable threshold level, or a selected value between the minimum perception and maximum tolerable threshold levels, the examiner considers the stimulation to be within a range of safety".

Therefore, as previous indicated since the Applicant discloses "Safety to the patient is gauged by an expectation that the treatment does not diminish the health of the patient". Thus, since a maximum tolerable level is *expected* not to diminish the health of the patient, a maximum tolerable level does meet the requirements as set forth by the Applicant to be safe. Furthermore, a range between the minimum perceived level and the maximum tolerable level would thus, in accordance with the Applicants definition of safe, constitute a range of safety. Additionally, it can be assumed that

tolerable stimulation does not diminish the health of the patient since tolerable is considered to be acceptable with few side effects or risks.

Additionally the applicant argues that the examiner has not indicated in Mann where "if the first treatment therapy is safe, storing the first set of information for subsequent use". However, paragraph 20 on page 3 clearly states that "the invention is the ability to store adjustments made to stimulation levels for estimated electrode thresholds so that the system learns corrections to the estimated equalized levels". Therefore, Mann does disclose the ability to store a first set of information for subsequent use.

Therefore, for the reasons argued above as well as the rejection previously made of record, the examiner considers the pending claims to remain rejected.

Final Office Action at pages 2-3.

The Examiner further stated in the Advisory Action mailed October 30, 2009 (at page 2) that:

> Applicant argues that Mann does not discloses (sic, disclose) "safety limits" or "a range of safety". However as previously indicated by the examiner, Mann does discloses (sic, disclose) "safety limits" or a "range of safety." Furthermore, the Applicant attempts to distinguish how "tolerable" or "tolerability" is different from "safety" by employing paragraph 182. However, the examiner maintains that the definition of "safety" or "safety limits" do not exclude "tolerable or tolerability." Furthermore, such limitations (to exclude tolerable or tolerability) can not be construed upon the claims when not recited in the claims. The applicant has not set forth any special definition of "safety" or "safety limits" and therefore the claims must be taken in their broadest reasonable interpretation.

In other words, the Examiner is suggesting that even though the term safety is not mentioned in Mann and there is no discussion in Mann of assessing whether information is within a range of safety, the disclosure of Mann inherently discloses the concept of safety. Applicants respectfully submit however, that it is incorrect to equate comfort with safety.

Applicants are unaware of any support for the Examiner's propositions that "a maximum tolerable level is *expected* not to diminish the health of the patient [emphasis by the Examiner]" and that "a maximum tolerable level does meet the requirements as set forth by the Applicant to be safe." Notably, the Office Action has provided no support for such a proposition and logically the two are not the same. Indeed, Applicants respectfully submit that many types of treatments would be tolerable to a patient from a comfort standpoint but would be considered unsafe.

The final Office Action states that the Applicant describes on page 14, paragraph 125, "the treatment therapy configuration is within a configuration range of safety. Safety to the patient is gauged by an expectation that the treatment does not diminish the health of the patient." The final Office Action jumps the conclusion that in all instances "[s]ince the stimulation is in a range of a minimum perception threshold level, a maximum threshold level, or a selected value between the minimum perception and maximum tolerable threshold levels, the examiner considers the stimulation to be within a range of safety." Again, the Office Action has provided no support for such a proposition and logically the two are not the same. Indeed, Applicants respectfully submit that many types of treatments tolerable to a patient from a comfort standpoint, but would be considered unsafe. Applicants also respectfully submit that many types of treatment would not be perceived by a patient but would be considered safe.

The rejection of claim 1 disregards the written specification as originally filed and the language of dependent claim 4, which differentiates what is "tolerable to the patient" from "a range of safety." For example, the specification as originally filed states (at page 55, paragraph [170] (which corresponds to the paragraph [0182] of the application published as US 2004/0138516)):

> In step 2705, a beginning of a detection cluster is recognized in accordance with the seizure detection algorithm 800. Detection of a seizure will trigger delivery of a treatment therapy (in this case stimulation), which may be redelivered during a detection cluster (e.g., cluster duration 2205) until the seizure has been terminated or **safety limits** (such as maximum stimulation on time per given period of time) **have been reached or tolerability becomes an issue**. [Emphasis added].

The final Office Action's reliance upon Mann is misplaced since the portion of Mann relied upon for the rejection is in the context of a pain therapy, and Mann's aim was to identify a perception threshold, a step that is not required by or necessary for practicing independent claims 1 and 25 of the present application. *See* Mann, Abstract, and paragraphs [0009], [0013], [0057], and [0076]. A minimum perception level or a maximum tolerable level of a treatment (including electrical brain stimulation) cannot be considered or used as a safety limit, especially for neuro-stimulation, since most of the cortical surface and subcortical structures are devoid of sensory receptors or of sensory functions. The concept of "minimum perception" or "maximum tolerability" applied to the brain would likely (if not inevitably) lead to brain tissue damage except possibly in the sensory cortex.

The Examiner maintains that "the definition of safety limits do not exclude tolerable or tolerability". The Examiner's argument does not hold for therapies delivered directly to the brain or for a large number of drugs administered systemically, since safety is poorly correlated with tolerability. That is, safe stimulation (e.g., that which would neither cause tissue damage nor adversely affect cognitive, behavioral, psychiatric or systemic (cardiovascular, respiratory, etc.) functions or increase seizure frequency or severity or create new epileptogenic zones), may not be perceived by a patient, which unsafe stimulation (e.g., that which causes tissue damage or adversely affects cognitive, behavioral, psychiatric or systemic (cardiovascular, respiratory, etc.) functions or seizures) may be tolerable to the patient.

For example, tissue damage may occur without immediate or even delayed symptoms or noticeable changes (signs) in the patient's neurologic or systemic health, and symptoms or signs of dysfunction (e.g., high blood pressure, certain cardiac arrythmias, S-T segment elevation, Q-T segment prolongation, etc.) may be caused by stimulation that does not exceed the charge density limits but is tolerable to the patient. In other words, the patient may be unaware that brain tissue is being destroyed or that his cardiovascular system is negatively impacted since these untoward reactions may not reach a perception threshold. This applies not only to neuro-stimulation but also to medical disorders in general; for example, patients are typically unaware of having high blood pressure or certain types of arrythmias or EKG abnormalities. **The examiner ignores the fact that tolerability does not ensure safety, and ignores that safety does not ensure tolerability in the case of electrical brain stimulation and of therapeutic interventions in general.**

Safety in the present application has at least three dimensions all objective and quantifiable: (1) Protect the integrity of the brain tissue under stimulation by not exceeding a charge density; (2) Avoid paradoxical effects of stimulation on seizure frequency and severity and the generation of new epiletpogenic zones; and (3) Preserve the subjects' general health. Brain stimulation may have adverse effects (cardiovascular, cognitive, psychiatric, etc.) that are not perceived/perceivable by the patient, at currents that do exceed or do not exceed the safety limit.

Tolerability in the present application is an entirely subjective matter; patients may determine that a safe stimulation is not tolerable (e.g. it makes them feel funny), even though there is no evidence of cognitive dysfunction or of ECoG, EKG, heart rate, blood pressure or respiratory abnormalities.

The distinctions between safety and tolerability in the context of the present invention is further shown in the following excerpts from the present application (at paragraphs [0113], [0121], [0122], [0123], [0125], [0126], [0138], [0139], and [0148] of the application as published as US Publication No. 2004/0138516, which corresponds to the specification as originally filed at pp. 32-45, at paragraphs [0109], [0116], [0117], [0117], [0119], [0120], [0131], [0132], and [0140]):

> [0113] In step 2153, the physician inputs an electrode configuration in accordance with the electrographic spread and the seizure focus location that is presented to the physician in steps 2017 and 2025. In another embodiment of the invention, the medical device system provides a recommendation of the electrode configuration to the physician in accordance to the electrographic spread and the seizure focus location. The physician may accept, reject, or modify the recommendation. A "perform_manual_stimulation" step 2155 comprises sub-steps 2159 and 2161. The physician defines electrode polarities and stimulation parameters. (In an embodiment, an electrode polarity may be classified as a stimulation parameter. ***
>
> [0121] The medical device system may have a "manual" treatment therapy mode that is different from a normal run mode (automated mode), in that stimulations may be delivered by the user, in order to test the clinical efficacy and tolerability of therapy configurations. In the manual treatment therapy mode, the medical device system may enable the user to select parameters (i.e., intensity, frequency, and pulse width), therapy element configurations, to assess charge density, to test treatment therapy levels, to insure safety to the patient, and to determine efficacy and tolerability. ***
>
> [0122] Before a user-defined treatment therapy configuration is even tested or stored, the medical device system preferably performs a charge density check. For example, in the embodiment of electrical stimulation therapy, the medical device system computes the charge density of the stimulation configuration using the impedance of the electrode configuration, voltage level, stimulation pulse width and contact geometry of the electrode configuration. The charge density may be computed using the following formula:
>
> $$(I \cdot \Delta w)/(\text{surface area of electrode})$$
>
> [0123] where I is the current of the stimulation pulse and is approximately equal to the voltage level divided by the impedance, and Δw is the pulse width. If the calculated charge density exceeds a preset threshold, the medical device system

considers the stimulation configuration to be not valid and prevents and/or warns the user from testing with the associated stimulation configuration. ***

[0125] If a treatment therapy configuration is within a permissible charge density range, the medical device system allows the user to test the treatment therapy configuration. During a test, the user is able to use a start/stop delivery capability of the medical device system. If the delivery is not terminated by the user, the medical device system continues to deliver treatment therapy for the specified time duration. The medical device system then queries the user whether or not the treatment therapy configuration was acceptable. The user (e.g., patient or physician care-giver) responds with a "yes" or "no" through programmer 109. In other embodiments, a treatment therapy level that is beyond the point at which the user stops delivery is considered as not tolerated by the patient. Moreover, the medical device system may insure that the treatment therapy configuration corresponds to a treatment that is safe to the patient, where the treatment therapy configuration is within a configuration range of safety. Safety to the patient is gauged by an expectation that the treatment does not diminish the health of the patient.

[0126] In the embodiment where the medical device system is providing treatment of seizure disorders, the medical device system operates seizure detection algorithm 800 in real-time during the manual stimulation mode, as in the normal run mode, but with detection-triggered stimulation disabled. When selecting stimulation parameters for therapy use, the medical device system allows the user to select from a list of stimulation parameter configurations, which have been previously defined and tested in the manual stimulation mode. The user may be restricted to selecting only those stimulation configurations that were tolerated by the subject during testing in the manual stimulation mode. Once configured, the medical device system may return to normal mode of operation to provide detection-triggered stimulation in accordance with the stimulation configuration set by the users.

***

[0138] ... External system 100 is programmed not to accept stimulation parameter values that exceed a pre-specified current density or the toleration limits as determined in step 1961.

[0139] If one or more measures of seizure activity exceed a predetermined limit at any point in time, e.g., the 99% tile value of preceding detections, the event may be an indication that therapy may have a paradoxical effect. ***

[0148] During its operation, the medical device system may also invoke any number of methods for limiting therapy during operation if it would result in therapy being outside of the acceptable range for one or more therapy parameters. For example, in the embodiment of the external system 100, the system 100 may limit the total number of stimulations delivered for a variety of reasons including, but not limited to, programming checks and lockouts, tissue damage, and run time

monitoring and control. During programming of the external system 100, the programmer software checks the programming information to make sure that the stimulation board (e.g., Synergy®) never provides a charge density above a predetermined limit (e.g., 30 $\mu C/cm^2$/phase). In particular, the programmer software performs calculations based on the geometry of the lead being used and the attempted setting entered by the user. If this predetermined limit is exceeded, a message informs or warns the user/clinician and prevents the parameters from being sent to the stimulation board.

In accordance with the specification, a "range of safety" as claimed in independent claim 1 is different than what is tolerable to a patient. Claim 4 states:

> [t]he method of claim 1, further comprising:
>
> (f) receiving an indication from the user whether the first treatment therapy is tolerable to the patient; and
>
> (g) if the first treatment therapy is not tolerable, executing a corresponding action.

Claim 4 shows that what may be tolerable to the patient is indeed different from "a range of safety" as claimed in independent claim 1. Claim 1 is directed toward a method that includes the step of "assessing whether the first set of information is within a range of safety." (emphasis added). The final Office Action suggests that Mann disclosed this, pointing to page 2, paragraph 12 of Mann, in particular, "a clinician using such neural stimulation system may immediately jump between two or more electrode sets, each of which has the stimulation magnitude levels automatically adjusted to, e.g., a minimum perception threshold level, a maximum tolerable threshold level, or a selected value between the minimum perception and maximum tolerable threshold levels." (Mann, pg. 2, para. [0012]) (emphasis added). The final Office Action states that Mann thus discloses a range between the minimum perception threshold level and the maximum tolerable threshold level, which the Applicants agree with.

In addition to the lack of support for the general proposition that comfort equates to

safety, here such a suggestion simply fails to address the feature "assessing whether the first set of information is within a range of safety" recited in claim 1. For example, as discussed on pp. 35-37, paragraphs 116-120 of the specification as filed (corresponding to paragraphs 121-126 of the application published as US Pub. No. 2004/0138516), charge density is based on the shape and configuration of the electrode as well as the stimulation applied. This is distinct from the concept of comfort or the determination of a magnitude of voltage or current that may be delivered (as is discussed in paragraph 12 of Mann). Thus, a comfortable stimulation for the patient in a first electrode might be safe while a similar stimulation in a second electrode (which would still feel comfortable because it was the same magnitude) might be unsafe. Consequentially, a stimulation level that the patient would perceive as being with a tolerable range (e.g. comfortable) might be unsafe, depending on how it was applied. Thus, an assessment that a treatment is comfortable does not address the issue of whether that treatment is safe. In particular, the specification as filed explains on pg. 37, ¶ 119 (corresponding to paragraph 125 as published in US Pub. No. 2004/0138516) that "[s]afety to the patient is gauged by an expectation that the treatment does not diminish the health of the patient" and it is not possible to determine whether a "comfortable" treatment will or will not diminish the health of the patient.

Furthermore, as noted on pg. 35, paragraph 116 in of the specification as filed (corresponding to paragraph 121 as published in US Pub. No. 2004/0138516), treatment parameters could include a number of variables such as stimulation time, pulse shape, etc. Therefore, additional safety issues such as charge balancing, see specification as filed at pg. 36-37, paragraphs 117-120 (corresponding to paragraphs 122-126 as published in US Pub. No. 2004/0138516), and the like could arise, making what was otherwise a comfortable treatment unsafe.

The basis for the Office Action's rejection of claim 1 is that comfort can be equated with safety. However, for at least the reasons discussed above, it is incorrect to equate something being comfortable for or perceived by the patient with something being safe. Therefore, the Office Action has failed to provide support that Mann inherently discloses "assessing whether the first set of information is within a range of safety" as recited in claim 1 and this rejection cannot fairly be maintained.

B. Independent Claim 1 Recites the Feature "if the first treatment therapy is not safe, executing a corrective action" And No Support Has Been Provided For The Suggestion That Mann Discloses This Feature.

Claim 1 further recites the feature of "if the first treatment therapy is not safe, executing a corrective action." Applicants submit that the Office Action did not provide any support for Mann disclosing this feature of claim 1. In this regard, Applicants note that rejection appears to rely on the incorrect premise that comfort is the same as safety. However, as noted above, an otherwise comfortable stimulation might not be safe. In other words, Mann could increase stimulation to a level that was comfortable (e.g. provided an acceptable level of treatment for a particular symptom based on the magnitude of the stimulation) while at the same time providing a stimulation that was unsafe. Furthermore, the Examiner has failed to provide any support for the suggestion that Mann discloses taking a corrective action, nor does Mann appear to disclose taking a corrective action.

Therefore, for at least the above reason Mann cannot be said to disclose the feature "if the first treatment therapy is not safe, executing a corrective action" as recited in claim 1. Thus, for this additional reason the rejection of claim 1 is not supported.

C. Claim 1 Recites the Feature "if the first treatment therapy is safe, storing the first set of information for subsequent use" and the Rejection Has Failed to Provide Any Support for the Suggestion that Mann Discloses This Feature.

Claim 1 recites the feature "if the first treatment therapy is safe, storing the first set of information for subsequent use." The Examiner failed to point to any disclosure in Mann as disclosing this feature. The Final Office Action cites to paragraph 20 on page 3 of Mann for this feature, but Mann only teaches storing adjustment for estimated electrode thresholds as perceived by the patient, not storing a set of information if the first treatment therapy is safe. Thus, to date there has been no support provided for the suggestion that Mann discloses this feature of claim 1. Consequentially, the Examiner has not met the burden of providing a basis for the rejection of claim 1 based on Mann for this additional reason.

D. Claims 7-11 Are Patentably Distinct Over Mann and the Examiner Improperly Ignored the Prior Indication of Why These Claims Are Not Merely Obvious Design Choices.

The Office Action admits that Mann fails to disclose the feature of claims 7-11 but suggests that claims 7-11 are obvious in view of Mann anyway because, while Mann fails to disclose the recited features, there is allegedly no disclosure regarding the advantages of such an approach. As previously submitted, however, the features of claim 7-11 are not merely design choices and advantages have been provided for the recited features. Thus, the rationale used by the Examiner in rejecting claims 7-11 is not supported and is inconsistent with the support provided for why the claimed features are patentably distinct.

1. No Support Has Been Provided for the Suggestion That the Features of Claim 7 are a Design Choice.

Claim 7 recites the feature of "receiving the first label from the user" and further recites the feature of "applying a subsequent treatment therapy in accordance with the first label." The Examiner suggested these features were design choices. However, the suggestion is without support. The Examiner has provided no support for the proposition that such a feature is normally considered a design choice (such as has been held for cases where claims merely recite a minor shape change). In addition, potential advantages of the claims were previously provided. For example, one potential advantage of receiving labels from the user, as recited in claim 7, is that it can help simplify the selection of treatment options, which would otherwise be so numerous as to make selection difficult. The Examiner failed to address this issue and in view of the lack of any other support (legal or factual) for the rejection, it cannot properly be maintained.

2. No Support Has Been Provided for the Suggestion That the Features of Claims 8-11 are Design Choices.

Claim 8 recites the feature of "receiving another set of information from the user, the other set of information being associated with another treatment therapy configuration" and further recites the feature of "associating another label with the other set of information" and further recites the feature of "comparing the first set of information and the other set of information." The Examiner suggested these features were design choices. However, the Examiner has provided no support for why such features can be considered merely a design choice. The claim features, for example, are not simple shape changes or a simple separation into two parts of what was known to be a single part. Indeed, the Examiner has failed to show these features were even known in the art. Furthermore, Applicants have expressly provided a basis for why these features are not merely design choices. For example, one potential

advantage of the recited features of claim 8 is the ability to compare different treatment therapy configurations before saving them. Given the limited memory for storing information and the potential confusion of having two treatments that are essentially the same, such a step allows for subsequent steps such as saving the information or providing a notification to the user, depending on whether the information is essentially unique. The Examiner's apparent overlooking of this information appears to be the only reason for why the rejection was maintained because once the information is considered, the purported rationale of the rejection fails – instead it becomes clear that the recited features are not obvious design choices.

Claims 9-11 depend from claim 8 and therefore also recite features that cause them to be patentably distinct in view of Mann for at least the above reasons and for the additional features recited therein. For example, claim 9 recites the feature of "if the other treatment therapy configuration is essentially unique, storing the other set of information and the other label" and the Examiner has failed to put forth a logical basis for why such a step would be considered an obvious design choice. In addition, claim 10 recites the feature of "if the other treatment therapy configuration is not essentially unique, outputting a notification to the user" and the Examiner has failed to put forth a logical basis for why such a step would be considered an obvious design choice.

E. The Rejection of Claims 14-16 and 32 Did Not Address the Features Recited in Claim 14, Thus the Rejection Fails to Make a *Prima Facie* Case of Obviousness.

Claim 14 recites the feature of "determining a surface area of the electrode" and further recites the feature of "determining a charge density that is associated with the electrode." The Examiner admitted that Mann fails to disclose this feature but suggested that Whitehurst corrected the deficiency. In particular, the Final Office Action suggested that disclosure of the

use of a relatively large electrode surface somehow disclosed the claim feature. Whitehurst merely discloses, however, the use of large electrodes:

> also requires electrodes with a relatively large surface area, so as to maintain safe levels of charge density and current density.

Whitehurst, pg. 3, ¶ 46. In particular, the Examiner has failed to point to any portion of Whitehurst as disclosing "determining a surface area of the electrode" or as disclosing "determining a charge density that is associated with the electrode." Applicants respectfully assert that merely suggesting that a large surface area is beneficial falls short of disclosing the recited features. In other words, the mere suggestion that larger currents require more surface area falls far short of disclosing the step of "determining a surface area of the electrode" recited in claim 14. For example, Whitehurst does not disclose any type of determining with respect to surface area of electrodes. The cited portion of Whitehurst also completely fails to disclose determining a charge density. Thus, the Office Action has failed to provide any support for these features being present in the references of record.

Claims 15-16, which depend from claim 14, also recite additional features related to the determining of charge density and current and the cited references make no mention of such steps. Claim 32 recites features similar to the above discussed features of claim 14. Accordingly, for at least the reasons discussed above, the references of record fail to disclose all the recited features and the rejection fails to present a prima facie case of obviousness.

F. The Rejection of Claims 18 and 19 is Not Supported by the Proposed Combination of Mann in View of Esteller.

Claim 18 recites the method of claim 1 "wherein the treatment utilizes drug infusion." Claim 19 recites the method of claim 18 "wherein the first input value is selected from the group consisting of a drug type, a drug dosage, at least one infusion site, an infusion rate, and a time of delivering the drug dosage." As explained above, Mann does not teach or suggest the method of claim 1. Esteller does not remedy the deficiencies in Mann with respect to claim 1. Thus, the combination of Mann, or the modified Mann as applied to claims 1-6, 12-13, 17, 20, 22-31, and 33-36 in view of Esteller as proposed in the final Office Action (at pages 8-9) does not render obvious the claimed inventions recited in claims 18 and 19.

G. The Rejection of Claims 28-31 is Inconsistent with the Examiner's Admission that Mann Fails to Disclose All the Features of Claim 8 and the Examiner's Rationale For the Rejection is Not Supported.

Claim 28 recites the feature of "receiving another set of information from the user, the other set of information being associated with another treatment therapy configuration" and the feature of "associating another label with the other set of information" and the feature of "comparing the first set of information with the other set of information." These features are similar to the features recited in claim 8. The Examiner admitted that Mann failed to disclose these features when discussing claim 8, a point with which Applicants agree (*e.g.*, Mann fails to disclose the features of claim 8). The Examiner suggested, however, that Mann somehow does disclose the features of claim 28, stating:

using an implanted system with an external controller as described above. With reference to claims 28-31, Mann teaches multiple electrode sets, each labeled, with associate threshold data for the minimum perceived data and maximum tolerable data (see page 5, paragraphs 47-48). Mann further teaches that a subset of the possible electrode configurations may be measured and from such measurements estimates may be made of the unmeasured thresholds with accuracy (page 3, paragraphs 17-19).

Final Office Action, pages 6-7. As can be readily appreciated, however, the alleged disclosure of Mann falls short of disclosing the recited features of claim 28. For example, there is no suggestion that a label is applied to another set of information received from the user, nor is there any suggestion of comparing the first set of information with the other set of information. Instead, Mann at most discloses receiving sets of information without comparing them to prior received sets of information. In other words, the system of Mann would have no idea that two sets of information were basically identical. Also, sensory thresholds may vary as a function of factors such as level of arousal, attention and time of day, thus making comparisons meaningless under certain conditions. That is, electrical currents of the same intensity delivered to the same site, may be differently perceived by a subject due to factors such as level of arousal, attention and time of day. Furthermore, Mann completely fails to disclose the additional features of claims 29-31. Thus, the rationale used to reject claims 28-31 lacks support.

H. The Rejection of Claim 25 (and claims 26-31 and 33-36) is Not Properly Supported Because The Examiner Has Failed to Show That Mann Expressly or Inherently Discloses "An apparatus ... comprising in combination" the Features Recited in Claim 25.

Claim 25 recites an apparatus that includes a number of features and further includes a processor programmed to perform certain steps. As noted above with regard to claim 1, the

Examiner has failed to provide support that Mann discloses a system that performs these steps. In addition to this rationale, the rejection of claim 25 also fails to be properly supported as the Examiner has not pointed to any location in Mann that discloses an apparatus as claimed. In other words, even if the Examiner had properly shown support for the rejection of claim 1, which was not done, the suggestion that Mann discloses an apparatus with the features recited in claim 25 is not supported. In particular, the Examiner has only pointed to a clinician as allegedly performing certain steps recited in claim 25. Thus, even if the Examiner position was supported, which it is not, Mann would still fail to disclose the features recited in claim 25. Thus, for this additional reason claim 25 (as well as the claims that depend from claim 25) is patentably distinct in view of Mann.

VIII. Conclusion

The rejections contained in the Final Office Action of July 21, 2009 should be reversed for at least the reasons recited above. Reversal of the rejections is requested.

Respectfully submitted,

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CLAIMS APPENDIX

1. A method for configuring and testing therapy parameters for a treatment of a nervous system disorder with a medical device system, the medical device system being in a manual treatment therapy mode, the method comprising:

(a) receiving a first set of information from a user, the first set of information being associated with a first treatment therapy configuration;

(b) assessing whether the first set of information is within a range of safety;

(c) applying a first treatment therapy to a patient in accordance with the first set of information;

(d) if the first treatment therapy is not safe, executing a corrective action; and

(e) if the first treatment therapy is safe, storing the first set of information for subsequent use.

2. The method of claim 1, wherein (d) comprises:

preventing re-delivery of the first treatment therapy.

3. The method of claim 1, wherein (d) comprises:

terminating the first treatment therapy.

4. The method of claim 1, further comprising:

(f) receiving an indication from the user whether the first treatment therapy is tolerable to the patient; and

(g) if the first treatment therapy is not tolerable, executing a corresponding action.

5. The method of claim 1, further comprising:

(f) applying a subsequent treatment therapy in accordance with the first set of information.

6. The method of claim 1, further comprising:

(f) associating a first label with the first set of information.

7. The method of claim 6, further comprising:

(g) receiving the first label from the user; and

(h) applying a subsequent treatment therapy in accordance with the first label.

8. The method of claim 6, further comprising:

(g) receiving another set of information from the user, the other set of information being associated with another treatment therapy configuration;

(h) associating another label with the other set of information; and

(i) comparing the first set of information and the other set of information.

9. The method of claim 8, further comprising:

(j) if the other treatment therapy configuration is essentially unique, storing the other set of information and the other label.

10. The method of claim 8, further comprising:

(j) if the other treatment therapy configuration is not essentially unique, outputting a notification to the user.

11. The method of claim 8, further comprising the step of:

(j) if the other treatment therapy configuration is not essentially unique, rejecting the second set of information.

12. The method of claim 1, wherein the first treatment therapy configuration comprises at least one attribute selected from the group consisting of an electrode configuration, a stimulation parameter, a test treatment therapy level, an indication about safety to the patient, and a level of tolerability by the patient.

13. The method of claim 12, wherein the stimulation parameter is selected from the group selected from a voltage level of a stimulation pulse, a pulse width of the stimulation pulse, a duration of a stimulation pulse train, a polarity configuration of electrodes, a set of electrodes that is used, and a stimulation frequency.

14. The method of claim 1, wherein the first set of information comprises a voltage level of a stimulation pulse, a pulse width of the stimulation pulse, and a configuration of electrodes designating a set of electrodes, the set of electrodes comprising an electrode, the method further comprising:

(f) determining a surface area of the electrode;

(g) determining a charge density that is associated with the electrode; and

(h) if the charge density is greater than a predetermined threshold, rejecting the first set of information in order that the first treatment therapy corresponding to the first set of information is not delivered to the patient.

15. The method of claim 14, wherein the charge density is approximately equal to a current multiplied by the pulse width of the stimulation pulse divided by the surface area of the electrode.

16. The method of claim 15, wherein the current is approximately equal to the voltage level of the stimulation pulse divided by an impedance of the set of electrodes.

17. The method of claim 1, further comprising:

(f) transitioning operation to a run mode;

(g) receiving a subsequent set of information from the user, the subsequent set of information being associated with a subsequent treatment therapy configuration; and

(h) if the first treatment therapy is not acceptable and if the subsequent set of information corresponds to a subsequent treatment therapy that exceeds a corresponding level of tolerance associated with the first treatment therapy, rejecting the subsequent set of information.

18. The method of claim 1, wherein the treatment utilizes drug infusion.

19. The method of claim 18, wherein the first input value is selected from the group consisting of a drug type, a drug dosage, at least one infusion site, an infusion rate, and a time of delivering the drug dosage.

20. The method of claim 1, wherein the nervous system disorder is selected from the group consisting of a disorder of a central nervous system, a disorder of a peripheral nervous system, a mental health disorder, and psychiatric disorder.

21. The method of claim 20, wherein the nervous system disorder is selected from the group consisting of epilepsy, Parkinson's disease, essential tremor, dystonia, multiple sclerosis (MS), anxiety, a mood disorder, a sleep disorder, obesity, and anorexia.

22. The method of claim 1, wherein the first treatment therapy is selected from the group consisting of electrical stimulation, magnetic stimulation, drug infusion, and brain temperature control.

23. The method of claim 1, wherein the first treatment therapy is provided to a location of a body selected from the group consisting of a brain, a vagal nerve, a spinal cord, and a peripheral nerve.

24. The method of claim 1, wherein the medical device system is selected from the group consisting of an external system, an implanted system, and a hybrid system.

25. An apparatus for configuring and testing therapy parameters for a treatment of a nervous system disorder with a medical device system, the apparatus comprising in combination:

a user interface;

a treatment therapy module;

a memory; and

a processor that is connected to the user interface in order to receive a command from a user and to send a response to the user and that instructs the treatment therapy module, the processor configured to perform:

(a) receiving a first set of information from the user through the user interface, the first set of information being associated with a first treatment therapy configuration;

(b) assessing whether the first set of information is within a range of safety;

(c) applying a first treatment therapy to a patient through the treatment therapy module in accordance with the first set of information;

(d) if the first treatment therapy is not safe, executing a corrective action; and

(e) if the first treatment therapy is safe, storing the first set of information in the memory, wherein the first set of information is accessible for a subsequent treatment therapy.

26. The apparatus of claim 25, wherein the processor is configured to perform:

(f) receiving an indication from the user whether the first treatment therapy is tolerable to the patient; and

(g) if the first treatment therapy is not tolerable, executing a corresponding action.

27. The apparatus of claim 25, wherein the processor is configured to perform:

(f) associating a first label with the first set of information.

28. The apparatus of claim 27, wherein the processor is configured to perform:

(g) receiving another set of information from the user, the other set of information being associated with another treatment therapy configuration;

(h) associating another label with the other set of information; and

(i) comparing the first set of information with the other set of information.

29. The apparatus of claim 28, wherein the processor is configured to perform:

(j) if the other treatment therapy configuration is essentially unique, storing the other set of information and the other label.

30. The apparatus of claim 28, wherein the processor is configured to perform:

(j) if the other treatment therapy configuration is not essentially unique, outputting a notification to the user.

31. The apparatus of claim 28, wherein the processor is configured to perform:

(j) if the other treatment therapy configuration is not essentially unique, rejecting the second set of information.

32. The apparatus of claim 25, wherein the first set of information comprises a voltage level of a stimulation pulse, a pulse width of the stimulation pulse, a frequency of stimulation pulses, a duration of a stimulation pulse train, and a configuration of electrodes, the configuration of electrodes corresponding to a set of electrodes, the set of electrodes comprising an electrode, and wherein the processor is configured to performs:

(f) determining a surface area of the electrode;

(g) determining a charge density that is associated with the electrode; and

(h) if the charge density is greater than a predetermined threshold, rejecting the first set of information in order that the first treatment therapy corresponding to the first set of information is not delivered to the patient.

33. The apparatus of claim 25, wherein the processor is configured to perform:

(f) transitioning operation to a run mode;

(g) receiving a subsequent set of information from the user through the user interface, the subsequent set of information being associated with a subsequent treatment therapy configuration; and

(h) if the first treatment therapy is not acceptable and if the subsequent set of information corresponds to a subsequent treatment therapy that exceeds a corresponding level of tolerance associated with the first treatment therapy, rejecting the subsequent set of information.

34. A computer-readable medium having computer-executable instructions for performing the method recited in claim 1.

35. A computer-readable medium having computer-executable instructions for performing the method recited in claim 4.

36. A computer-readable medium having computer-executable instructions for performing the method recited in claim 5.

37. A computer-readable medium having computer-executable instructions for performing the method recited in claim 8.

EVIDENCE APPENDIX

-- NONE --

RELATED PROCEEDINGS APPENDIX

-- NONE --